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PATENT  
ATTORNEY DOCKET: 46884-5455

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
Masataka NISHIKAWA, et al. ) Confirmation No.: 2773  
)  
Application No.: 10/568,685 ) Group Art Unit: 1651  
)  
Filed: February 17, 2006 ) Examiner: Unassigned  
)  
For: READER FOR )  
IMMUNOCHROMATOGRAPHIC )  
TEST, CARTRIDGE APPLICABLE TO )  
THIS, AND SYSTEM FOR )  
EXAMINING )  
IMMUNOCHROMATOGRAPHIC )  
TEST PIECE )

Commissioner for Patents  
U.S. Patent and Trademark Office  
Alexandria, VA 22314

Sir:

**SUBMISSION OF INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY**

Applicants bring to the attention of the Examiner the attached document.

Attached is an English-language translation of an International Preliminary Report on Patentability ("IPRP") dated August 3, 2006 that issued in a related PCT/JP2004/015806 application. Applicants respectfully request that the Examiner consider the IPRP as it relates to the above-identified application.

While the IPRP cites to JP 2002-228662, JP 2003-043051, JP 2003-287535, JP 2002-22742, JP 11-83745, WO 2001/061340 and JP 2002-531827, these documents are not attached hereto because they were previously filed in an Information Disclosure Statement in this application on February 17, 2006.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If it should be determined that the listed documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0573. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

**DRINKER, BIDDLE & REATH LLP**

Dated: September 12, 2006

By:



Paul A. Fournier

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From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

HASEGAWA, Yoshiki  
SOEI PATENT AND LAW FIRM, Ginza First Bldg., 10-6,  
Ginza 1-chome, Chuo-ku, Tokyo  
1040061  
JAPON

Date of mailing (*day/month/year*)

03 August 2006 (03.08.2006)

Applicant's or agent's file reference

FP04-0361-00

**IMPORTANT NOTIFICATION**

International application No.

PCT/JP2004/015806

International filing date (*day/month/year*)

25 October 2004 (25.10.2004)

Applicant

HAMAMATSU PHOTONICS K.K. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP04-0361-00	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/015806	International filing date ( <i>day/month/year</i> ) 25 October 2004 (25.10.2004)	Priority date ( <i>day/month/year</i> ) 29 October 2003 (29.10.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant HAMAMATSU PHOTONICS K.K.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 24 July 2006 (24.07.2006)
Facsimile No. +41 22 338 82 70	Authorized officer  <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div> e-mail: pt07@wipo.int

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

**TRANSLATION**

**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference  
**FP04-0361-00**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.  
**PCT/JP2004/015806**

International filing date (day/month/year)  
**25.10.2004**

Priority date (day/month/year)  
**29.10.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant  
**HAMAMATSU PHOTONICS K.K.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/015806

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/015806

<b>Box No. V</b>	<b>Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</b>		
<b>1. Statement</b>			
Novelty (N)	Claims	1 - 19	YES
	Claims		NO
Inventive step (IS)	Claims	1 5	YES
	Claims	1 - 14, 16 - 19	NO
Industrial applicability (IA)	Claims	1 - 19	YES
	Claims		NO
<b>2. Citations and explanations:</b>			
<p>Document 1: JP 2002-228662 A (Hitachi, Ltd.), 14 August 2002</p> <p>Document 2: JP 2003-043051 A (Fuji Photo Film Co., Ltd.), 13 February 2003 &amp; US 2003/0003601 A</p> <p>Document 3: JP 2003-287535 A (Fuji Photo Film Co., Ltd.), 10 October 2003 &amp; US 2003/0186447 A</p> <p>Document 4: JP 2002-22742 A (Hamamatsu Photonics Kabushiki Kaisha), 23 January 2002</p> <p>Document 5: JP 11-83745 A (Matsushita Electric Industrial Co., Ltd.), 26 March 1999</p> <p>Document 6: WO 2001/061340 A (Matsushita Electric Industrial Co., Ltd.), 23 August 2001 &amp; US 2002/0138275 A &amp; EP 1172651 A</p> <p>Document 7: JP 2002-531827 A (Abbott Laboratories), 24 September 2002 &amp; WO 2000/033072 A</p>			
<p>Claims 1, 2, 1-14, 16, 17</p> <p>Document 1 describes a constitution wherein a cartridge used in immunological examination (132, 135, 137 in Fig. 10; equivalent to "test tools" in the invention of this application) is held by an adapter (see 133, 136, 138 in Fig. 10; equivalent to "cartridge" in this application's invention), thereby making it possible to insert cartridges with various configurations into an optical measurement device (131 in Fig. 10). It also describes a constitution wherein there is a region on the surface of the cartridge inserted in the optical measurement device that can magnetically memorize, and used information (equivalent to "information on immunochromatographic test tools") can be written to this region.</p> <p>An immunochromatographic test tool constituted to be held by a cartridge was well known when this application was filed (see documents 4 and 5). Employing an immunochromatographic test tool as the cartridge described in document 1 would easily be carried out by a person skilled in the art.</p> <p>Also, providing a through hole in order to extract a substance kept in a cartridge would be carried out by a person skilled in the art as required.</p>			



Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V.2

Claims 3-10, 18, 19

Document 2 (claims) and document 3 (drawings, paragraph 0017 and 0030) describe a constitution wherein an information holding means is provided on a measurement substrate or analysis element, and information related to measurement is recorded as the held information. Constituting matters so as to record information related to measurement, such as test tool identification, processing for reading the color region, reading method, data calculations, information related to the color region, etc. in the memory region described in document 1 would be carried out by a person skilled in the art as required.

Also, document 3 describes a constitution wherein a dot array pattern (equivalent to "marker for identifying test tools" in this application's invention) is provided on the surface of a test tool. Employing the constitution of document 3 in document 1 and providing a mark for cartridge identification on the surface of the adapter of document 1 would easily be carried out by a person skilled in the art as required.

Also, a constitution that provides a communication means in a test tool was well known when this application was filed (see documents 6 and 7). Providing an information transmission means in the adapter in the constitution of document 1 would be carried out by a person skilled in the art as required.

Claim 15

In a reading device for immunochromatographic test, constituting matters so that a cartridge through hole is exposed outside the reading device when the cartridge is introduced into the reading device is not described in any of the documents cited in the ISR and is not obvious to a person skilled in the art.